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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/899,432 | 07/06/2001 | Robert Kleiman | FLORA. 1100 | 3374 |

77037 7590 11/07/2008

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| EXAMINER | |
|---|---|
| KANTAMNENI, SHOBHA | |
| ART UNIT | PAPER NUMBER |
| 1617 | |
| MAIL DATE | DELIVERY MODE |
| 11/07/2008 | PAPER |

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/899432
Filing Date: 07/06/2001
Appellant(s): Robert Kleiman et al.

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**EXAMINER'S ANSWER**

This is in response to the appeal brief filed on 06/24/2008.

***(1) Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

***(2) Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

***(3) Status of Claims***

The statement of the status of the claims contained in the brief is correct.

***(4) Status of Amendments***

The appellant's statement of the status of amendments contained in the brief is correct.

***(5) Summary of claimed subject matter***

The summary of claimed subject matter contained in the brief is correct.

***(6) Grounds of Rejection to be Reviewed on Appeal***

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Grounds of Rejections to be Reviewed on Appeal:

1) Rejection of claims 91-92 under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al. (WO 9602244 A1), and further in view of ARQUETTE et al. (WO 9920224).

2) Rejection of claims 93-102 under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al., and further in view of ARQUETTE et al. (WO 9920224) as applied to claims 91-92 above, and further in view of Katz (4,874,794) or Katz (5,070,107).

***(7) Claims Appendix***

The copy of the appealed claims contained in the Appendix to the brief is correct.

***(8) Evidence Relied upon***

| | | |
|---|---|---|
| US 5,952,392 | Katz et al. | September 1999 |
| WO 9602244 A1 | Sintov et al. | Febraury 1999 |
| WO 9920224 | Arquette et al. | April 1999 |
| US 4,874,794 | Katz | October 1989 |
| US 5,070,107 | Katz | December 1991 |

***(9) Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al. (WO 9602244 A1), and further in view of ARQUETTE et al. (WO 9920224).

Katz et al. (5,952,392) discloses that long chain fatty acids broadly including oleic acid (C18, one double bond, see col.2 lines 12-15; col. 3, lines 5-8, col.4, lines 26-28; col.6, lines 28-35) or monounsaturated long chain alcohols broadly (e.g., C18-C28, or octadecenol, docosenol, brassidyl alcohol) in their effective amounts with a physiologically compatible carrier (e.g., cream or ointment applied to skin, or aqueous solution, see col. 12, EXAMPLE 5; Examples 12, 14-15, col.20 lines 34-35, and col.22 lines 39-40 and 64) are useful in a pharmaceutical composition for topical application, intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity. See abstract, col.1 lines 10-15 and 20-47; col.3 lines 18-21; col.7, lines 62-67; col. 12, EXAMPLE 5; Examples 14-15 at col.22-23. It is further disclosed that compositions therein for use in treating viral infections comprise active ingredient or combination of compounds as the active ingredients selected from a group consisting of saturated aliphatic alcohols, mono-unsaturated aliphatic alcohols, mono-unsaturated aliphatic amides and aliphatic acids having a carbon chain length of 18-28 carbons, wherein the active ingredient is present in an amount of 0.1 to about 50 % by

weight of the final composition. See column 6, lines 28-36, lines 50-55. It is taught that the compositions therein are administered to the skin or a mucous membrane topically, parenterally or by transmembranal penetration using a cream, lotion, gel, ointment, suspension, aerosol spray or semi-solid formulation (e.g., a suppository). See column 7, lines 62-67; column 24, claims 7-11.

The prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with the particular long chain fatty acids salts such as C20 acids, and fatty acid esters herein in a composition for treating virus-induced and inflammatory disease of skin and membranes.

Sintov et al. discloses topical pharmaceutical composition for the treatment of viral infections comprising salts of carboxylic acid which include alkali metal oleates, C18 acid salts. See abstract; page 2, bottom paragraph; pages 3, lines 1-3, paragraph 5; page 7, EXAMPLE 1.

Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), and the instant fatty acid esters in their various percentages (see pages 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12, especially claim 23). It is also taught that fatty acids such as oleic acid, myristic acid etc are used as emollients. See page 1, lines 24-29.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the instant particular fatty acids salts such as C20 acid salts to treat viral infections in the methods of Katz et al. because Katz et al. (5,952,392), and Sintov

et al., teach the use of C18 acids and salts (sodium salt of oleic acid) in the method of treating viral infections. One of ordinary skill in the art at the time of invention would have been motivated to utilize the fatty acid salts as instantly claimed because of an expectation of success similar to that taught for structurally similar prior art species i.e C18 acids, and salts, since structurally similar compounds usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species, In fact, similar properties may normally be presumed when compounds are very close in structure. Moreover, fatty acid and salts of fatty acids of Katz et al. (5,952,392), Sintov et al., and the instant particular fatty acid salts are homologs, and thus they possess same or substantially similar activities. Absent a showing of unexpected results, homologous compounds are considered to be obvious. In re Hass, 141 F.2d 127, 60 USPQ 548 (CCPA 1944), In re Henze, 85 USPQ 261 (CCPA 1950).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant long chain fatty acid salt in combination with long chain alcohols taught by Katz et al., in the method of treating virus-induced and inflammatory disease of skin and membranes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant long chain fatty acid salt in combination with long chain alcohols because 1) the instant long chain fatty acid salt is a homolog of

alkali metal oleate, and will possess similar anti-viral properties as that of alkali metal oleate, and 2) monounsaturated long chain alcohols are known to be useful to treat virus-induced and inflammatory disease of skin and membranes according to Katz et al. (5,952,392), and Sintov et al. Accordingly, one of ordinary skill in the art would have been motivated to combine long chain fatty acid salt and long chain alcohol with reasonable expectation success of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin and membranes.

It would have been obvious to a person of ordinary skill in the art at the time of invention to add instantly claimed fatty acid esters to the composition comprising monounsaturated long chain alcohols, and alkali metal salt of fatty acid because Arquette et al. teaches that the instantly claimed fatty acid esters are known to be used as emollients in pharmaceutical compositions. Thus, one of ordinary skill in the art at the time of invention would have been motivated to add the instantly claimed fatty acid esters taught by Arquette et al. to the composition comprising monounsaturated long chain alcohols, and salt of fatty acid with reasonable expectation of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin and membranes since salts of long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts with a physiologically compatible carrier are known to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant fatty acid esters taught by Arquette et al. with the monounsaturated fatty alcohols, and the salts of fatty acid in a pharmaceutical composition would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes because 1) fatty acid esters are known to be used as an emollients in pharmaceutical composition comprising monounsaturated long chain alcohols, and 2) further according to Arquette emollients have beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin. Thus, one of ordinary skill in the art would have been reasonably expected that the combination of the instant fatty acid esters taught by Arquette et al. with the instant fatty alcohols, and the salts of oleic acid i.e instant salts of fatty acids in a pharmaceutical composition would have at least additive therapeutic effects, and also provide additional benefits such as softening, smoothening of skin.

Claims 93-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al., and further in view of ARQUETTE et al. (WO 9920224) as applied to claims 91-92 above, and further in view of Katz (4,874,794) or Katz (5,070,107).

Katz et al., Sintov et al., and ARQUETTE et al. are as discussed above.

Katz et al. (5,952,392) does not explicitly teach the effective amount of monounsaturated alcohol as from about 0.1 mg to about 2 gm per 50 kg of body weight.

Katz et al. (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3 lines 63-68, claims 1-2.

Katz et al. (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, col.3 lines 63-68, claims 1-2.

One of ordinary skill in the art would have been motivated to optimize the effective amounts of instantly claimed long chain monounsaturated alcohols in the composition because Katz et al. '794, and '107 teaches effective amounts of structurally similar long chain fatty alcohols active agents for treating viral infections and skin inflammations as 0.1 mg to 2 g/per 50kg of body weight. Further, it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

***(10) Response to Argument***

1) Rejection of claims 91-92 under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al. (WO 9602244 A1), and further in view of ARQUETTE et al. (WO 9920224), should be affirmed.

Appellant argues that "Katz et al. (U.S. 5,952,392) does not disclose or teach use of" "a method for treating at least one of virus-induced and inflammatory diseases [...] comprising the step of providing a topical composition consisting essentially of at least one of octadecenol, eicosenol, docosenol, tetracosenol and hexacosenol in a concentration of from 0.1 to 25 percent by weight of an admixed physiologically active carrier; at least one salt of a jojoba-derived trans-free fatty acid according to the formula R1-COOM+, wherein: R1 comprises CH3(CH2)7CH=CHCH2(CH2)×; x is at least one of 8, 10, and 12; and M+ is a monovalent alkali metal ion; and at least one mixed ester according to the formula R2-COO-R3, wherein: R2 comprises CH3(CH2)7CH=CHCH2(CH2)y ; y is at least one of 6, 8, 10 and 12; and R3 is at least one of an alkyl group and an aliphatic group comprising between 1 to 12 carbon atoms" as required by claim 91 of the present invention. Further, Katz et al. (U.S. 5,952,392) does not teach or disclose any salts of fatty acids or mixed esters." See page 15, of the Brief.

In response, it is pointed out that applicant is arguing against a single reference when the rejection was based on combination of references. Katz et al. teaches that long chain fatty acids broadly including oleic acid (C18 one double bond), n-docosanoic acid (C22 acid, see column 3 of '392, lines 9-11) and long chain alcohols such as docosenol, brassidyl alcohol in their effective amounts in a topical pharmaceutical composition are useful in treating viral infection. Sintov et al. teach that salts of oleic acid are employed in treating viral infection. Arquette teaches that instant fatty acid esters are known to be used as emollients in topical pharmaceutical compositions and provide beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the instant particular fatty acids salts such as

C20 acid salts to treat viral infections in the methods of Katz et al. because Katz et al. teaches long chain fatty acids broadly including oleic acid (C18 one double bond), n-docosanoic acid (C22 acid, see column 3 of '392, lines 9-11) as having antiviral activity (5,952,392), and Sintov et al., teach the use of C18 acids and salts (sodium salt of oleic acid) in the method of treating viral infections. One of ordinary skill in the art at the time of invention would have been motivated to utilize the C20 fatty acid salts as instantly claimed in the method of treating viral infection because of an expectation of success similar to that taught for structurally similar prior art species i.e C18 acids, and salts, since structurally similar compounds usually have similar properties, and further Katz teaches that long chain fatty acids broadly including oleic acid (C18 one double bond), n-docosanoic acid (C22 acid, see column 3 of '392, lines 9-11) have antiviral activity. One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant long chain fatty acid salt in combination with long chain alcohols because 1) the instant long chain fatty acid salt (C20 acids) are structurally similar to alkali metal oleate (C18 acid), and will possess similar anti-viral properties as that of alkali metal oleate, and 2) monounsaturated long chain alcohols are known to be useful to treat virus-induced and inflammatory disease of skin and membranes according to Katz et al. (5,952,392). Accordingly, one of ordinary skill in the art would have been motivated to combine instant long chain fatty acid salt and long chain alcohol with reasonable expectation success of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin and membranes with at least additive effect. Further, one of ordinary skill in the art would have reasonably expected

that combining the instant fatty acid esters taught by Arquette et al. with the monounsaturated fatty alcohols, and the salts of fatty acid in a pharmaceutical composition as discussed above would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes, and also provide beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin effect because 1) fatty acid esters are known to be used as an emollients in topical pharmaceutical compositions comprising monounsaturated long chain alcohols, and 2) further according to Arquette emollients such as instant fatty acid esters have beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin.

Appellant argues that "Arquette et al. does not teach or disclose use of any salts of fatty acids in a topical composition, let alone the salts of fatty acids of the instant invention in combination with monounsaturated long chain alcohols and mixed esters in accordance with Appellants' invention." See page 16, of the Brief.

In response, it is pointed out that applicant is arguing against a single reference when the rejection was based on combination of references. Arquette et al. reference was employed for its teachings that the instantly claimed fatty acid esters are known to be used as emollients in topical pharmaceutical compositions, and provide beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin.

Appellant argues that "Sintov et al. teaches away from the salts in the present invention by stating that "[e]specialty preferred the use in the present invention is a water-solubilized C16-C18 carboxylic acid salt, such as alkali oleate." The salts of the present invention comprise salts of long chain fatty acids that are carbon chain lengths of 20 or greater." See page 18, of the Brief.

In response, it is pointed out that Sintov et al. does not teach away from employing the salts of long chain fatty acids that are carbon chain lengths of 20 or greater. Sintov et al. recites C16-C18 carboxylic acid salts as the preferred carboxylic acids in water as the medium. The instant claims do not limit to water as physiologically active carrier, and thus the solubility of carboxylic acids in water alone with different chain length is not relevant. Note that the physiologically acceptable carrier in the instant claims can be water, alcohol etc. or mixtures of different solvents. The solubility of carboxylic acids with different chain lengths in alcohol/water mixtures will be different from solubility in water. Further, it has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. Sintov et al. discloses topical pharmaceutical composition for the treatment of viral infections comprising salts of carboxylic acid. Further, it is pointed out that Katz (5,952,392) broadly teaches that long chain fatty acids which includes oleic acid, n-docosanoic acid (C22 acid) etc. have antiviral activity. See column 3, lines 8-11. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to utilize the fatty acid salts (C20 fatty acid salts) as instantly claimed because of an expectation of success similar to that taught for structurally similar prior art species i.e C18 acids, and salts, since structurally similar compounds usually have similar properties such as antiviral activities, and Katz

teaches that long chain fatty acids with a carbon chain length of greater than 20 have antiviral activity.

Appellant argues that "it is the fact that salts of longer chain fatty acids (greater than 18 carbons) are less soluble than salts of shorter-chain fatty acids. It follows that dramatic improved activity of the less soluble salts of longer-chain fatty acids in combination with the alcohols and mixed esters of the claimed invention is surprising, and could not have been expected based on the disclosure of Sintov et al." See page 18, of the Brief.

In response, it is pointed out that appellant has not provided any convincing data with respect to improved activity of the less soluble salts of longer-chain fatty acids in combination with the alcohols and mixed esters of the claimed invention. Appellant has merely provided data for the combination of jojoba derived fatty acid salts, monounsaturated alcohols and mixed esters of the claimed invention ('K100) as compared to the antiviral activity of the saturated alcohol alone, docosanol (C22 saturated alcohol). See Exhibits 1, 3, 4, provided by Appellant. No comparitive antiviral activity data has been provided for acids with carbon chain length of 20 or greater than 20 with acids of carbon chain length of 18 (C18, i.e shorter chain fatty acid).

Further, note that fatty acids derived from jojoba oil also contain C18 fatty acid. See EXHIBIT 1. Thus, it is not clear if the antiviral activity data provided for the combination by tha appellant is due to C18 fatty acid salt or C20 fatty acid salt or greater than C20 fatty acid salt, since all these fatty acids can be derived jojoba oil.

Appellant argues that "the suggested combination that the Examiner proposes does not appreciate the surprising, synergistic effects of the combination of the present invention, See Exhibits 5 and 6 (discussing the 100-fold increase in antiviral activity of the present invention as compared to the antiviral activity of the alcohol alone).

Notwithstanding that these affidavits clearly state that "K100 refers to the combination of monounsaturated long chain alcohols, jojoba-derived fatty acid salts, and fatty acid esters (specifically, jojoba esters)", the Examiner states that "the declaration does not provide any in information with respect to which unsaturated long chain alcohol, fatty acid salt, and ester are employed in the combination K100." See pages 21-22, of the Brief.

In response, it is pointed out that jojoba-derived fatty acid salts can be C18-fatty acid salt, since C18-fatty acids are derived from jojoba oil. It is pointed out that it is not clear as to which fatty acids salts are present in K100. Further, the 37 C.F.R. § 1.132 Affidavits by Robert Kleiman and David Ashley have been considered, but not found persuasive. The declaration does not provide any information with respect to which unsaturated long chain alcohol, fatty acid salt, and ester are employed in the combination composition K100, Exhibit 1, and the amounts of individual components employed in the combination composition K100. Further, there is no data provided for the individual fatty acid salts, and esters. The declaration merely provides antiviral activity data for n-docosanol alone which is a saturated alcohol not within the scope of instant claims which contain unsaturated alcohol, docosenol (C22 saturated alcohol). Thus, no antiviral activity data has been provided for the individual unsaturated alcohol, fatty acid salts, and esters. Accordingly, the data is not convincing with respect to the synergistic effects of the combination of the present invention, since there is no comparision data provided for instant combination with individual unsaturated alcohol, fatty acid salts, and esters.

It is pointed out that the data “100-fold increase in antiviral activity seen as a result of the combination of the present invention” is not convincing with respect to the synergistic effects of the combination of the present invention because appellant did not provide any data for individual unsaturated alcohol, fatty acid salts, and esters. As discussed above

appellant merely provides antiviral activity data for n-docosanol which is a saturated alcohol not within the scope of instant claims which contain unsaturated alcohol, docosenol. Thus, no antiviral activity data is provided for the individual unsaturated alcohol, fatty acid salts, and esters. It is no clear what the appellant is comparing with, to claim a 100-fold increase in antiviral actiivty of the combination of the present invention i.e is the 100-fold increase with respect to docosanol? If it is with respect to docosanol, the data is not commensurate in scope with instant claims which contain unsaturated alcohol, docosenol.

2) Rejection of claims 93-102 under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al., and further in view of ARQUETTE et al. (WO 9920224) as applied to claims 91-92 above, and further in view of Katz (4,874,794) or Katz (5,070,107), should be affirmed.

Examiner hereby incorporate and reiterates all arguments/remarks made under the previous section relating to the rejection of claims 91-92 under, 103(a) in this section.

Appellant argues that "Appellants respectfully submit that optimization of the teachings of the Katz et al. ('392, '794, '107) references would not result in the combination of Appellant's invention. As discussed at length above, the combination of the present invention could not have been deduced from the prior art, nor was the nature of the synergistic effect of the combination of" the present invention known or appreciated in the prior art. See Exhibits 5 and 6. Specifically, data presented in Exhibits 5 and 6 show an at least 100-fold increase in antiviral effectiveness against the HSVI strain (6343)." See pages 23-24, of the Brief.

In response, it is pointed out that the data "100-fold increase in antiviral activity seen as a result of the combination of the present invention" is not convincing with

respect to the synergistic effects of the combination of the present invention because appellant did not provide any data for individual unsaturated alcohol, fatty acid salts, and esters. As discussed above appellant merely provides antiviral activity data for n-docosanol which is a saturated alcohol not within the scope of instant claims which contain unsaturated alcohol, docosenol. Thus, no antiviral activity data is provided for the individual unsaturated alcohol, fatty acid salts, and esters. It is no clear what the appellant is comparing with, to claim a 100-fold increase in antiviral activity of the combination of the present invention i.e is the 100-fold increase with respect to docosanol? Accordingly, the antiviral activity data is not convincing with respect to the synergistic and suprising effects of the combination of unsaturated alcohol, fatty acid salts, and esters, since the appellant has not compared the combination data with the individual unsaturated alcohol, fatty acid salts, and esters.

As discussed in the rejection above, one of ordinary skill in the art would have been motivated to optimize the effective amounts of instantly claimed long chain monounsaturated alcohols in the composition because Katz et al. '794, and '107 teaches effective amounts of structurally similar long chain fatty alcohols active agents for treating viral infections and skin inflammations as 0.1 mg to 2 g/per 50kg of body weight. Further, it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, it is believed that the rejections should be sustained.

***(11) Related Proceedings Appendix***
None

Respectfully submitted,

/SREENI PADMANABHAN/
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Conferees

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